UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, VIRGINIA, WASHINGTON, WISCONSIN, THE CITY OF CHICAGO, AND THE CITY OF NEW YORK *ex rel.* OMNI HEALTHCARE INC.,

Plaintiffs,

v.

MCKESSON CORPORATION, MCKESSON SPECIALTY CARE DISTRIBUTION CORPORATION, MCKESSON SPECIALTY DISTRIBUTION LLC, MCKESSON SPECIALTY CARE DISTRIBUTION JOINT VENTURE, L.P., ONCOLOGY THERAPEUTICS NETWORK CORPORATION, ONCOLOGY THERAPEUTICS NETWORK JOINT VENTURE, L.P., US ONCOLOGY, INC., and US ONCOLOGY SPECIALTY, L.P.,

Defendants.

Case No.: 12-CV-06440(NG)(LB)

OMNI HEALTHCARE INC.'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Rules

Other Authorities

Relator Omni Healthcare Inc. ("Omni" or "Relator") respectfully submits this memorandum of law in opposition to Defendants' (hereinafter collectively "McKesson") Motion to Dismiss Relator's Second Amended Complaint ("SAC").

PRELIMINARY STATEMENT

The primary focus of Defendants' motion to dismiss is their argument that this action is barred because of a previously filed action *United States ex rel. Underwood v. Amgen Inc*., No. 1:10-cv-02441 (E.D.N.Y.)[1], which was unsealed and voluntarily dismissed in 2016. Defendants' argument is completely lacking in merit.

"The first-to-file bar was intended to prevent relators from litigating parasitic suits that provide no additional benefit to the public and would simply represent a drain on the government's recovery." John T. Boese, Civil False Claims and Qui Tam Actions § 403[C][2] at 4-182. This action is not a parasitic lawsuit; it was filed in 2012 while the *Underwood* action was still under seal and relies on facts within the knowledge of the Relator, none of which are recited in the *Underwood* complaint.

More importantly, the *Underwood* complaint alleges a fraudulent scheme that is entirely independent from the fraudulent acts alleged here. *Underwood* alleges that a number of manufacturers (none of whom include McKesson) intentionally placed excess overfill in vials so as to induce providers to utilize the manufacturers' drugs. It also alleges that certain repackagers (none of whom include McKesson) acting as "middlemen," harvested overfill from the vials, and re-

[1] Defendants also cite *United States ex rel. Hanks v. Amgen, Inc.*, No. 1:08-cv-03096 (E.D.N.Y. Nov. 30, 2011) as another overfill case that's "pending" in this district involving the "same allegations" against "numerous oncology clinics", but that case is not "similar" as it involved accusations of improper kickback contracts between Amgen and other defendants concerning illegal tying arrangements and promotions for off-label use of certain drugs. *Hanks* was dismissed by this Court (2018 WL 4409832 (E.D.N.Y. Sept. 17, 2018)) after the *Hanks* relator agreed his complaint raised claims identical to those in *United States ex rel. Piacentile v. Amgen,* 2018 WL 4409838 (E.D.N.Y. Sept. 17, 2018).

packaged it to sell to providers. This case, in contrast, alleges that McKesson and its subsidiaries were distributors of drugs, and, acting on their own and without any connection to the manufacturers and re-packagers named in *Underwood*, harvested overfill from glass vials, placed it in syringes, and subsequently sold it to providers who billed the government for the illegally harvested overfill. Not only are the defendants (with one exception) completely different but the purpose of the fraud is different. *Underwood* alleges manufacturers intentionally added excess overfill to bribe providers to use their drugs. Omni alleges that McKesson, a distributor which did not manufacture vials, harvested overfill and sold it at a discount to providers.

Defendants seize upon one overlap in the two cases, which is the naming of US Oncology, Inc., an entity that McKesson acquired in December 2010—the very end of the time period that is the subject of this action and after *Underwood* was filed. *Underwood* alleges that US Oncology, Inc. was one of the healthcare providers to whom the various manufacturers or re-packagers (again, not including McKesson) sold overfill to in an effort to induce them to purchase those manufacturer's products. (*Underwood* Compl. ¶ 76.) However, McKesson's acquisition of US Oncology in late 2010 would not have put the government on notice of McKesson's or OTN's *own* illegal acts before that acquisition. Moreover, as described below, the allegations against US Oncology in this case are significantly different than those alleged against US Oncology, Inc. in *Underwood*.

As a result, and for the reasons stated below, *Underwood* could not have apprised the government of the allegations contained in this case—*i.e.*, the harvesting of overfill by McKesson and its various subsidiaries, and the sale of syringes to providers—and any recovery that could have been had in *Underwood* would not have compensated the government for the false claims alleged here. Thus, accepting *McKesson's* argument would immunize McKesson from any liability from its years-long fraudulent scheme.

Defendants have also failed to establish that the SAC should be dismissed for failure to state

a claim under Federal Rules of Civil Procedure 9(b) and 12(b)(6). For the reasons set forth below, this Court should reach the same conclusion.

FACTUAL BACKGROUND

Many drugs, including all the drugs that are the subject to this action, are packaged by the manufacturers in glass vials. (*See* SAC ¶ 102.) Many vials are designed to be used for a single dose for a patient and then discarded. (*Id.* ¶ 103.) To ensure that the full amount of the dose can be extracted from the vial and given to the patient, the vials typically contain a certain amount of overfill, above the prescribed dosage on the vial label. (*Id.* ¶¶ 106-09.) The Center for Medicare and Medicaid Services ("CMS") has made it clear that providers cannot bill Medicare and Medicaid for the use of overfill because the provider is not charged by the manufacturer for overfill. (*Id.* ¶¶ 112-16, 120-25.) The SAC in this case alleges that Defendants intentionally broke into the single-dose vials, harvested the dosage and overfill, and then sold syringes, with the discounted overfill, to providers who then billed Medicare and Medicaid for overfill. (*Id.* ¶¶ 6-7, 10, 13, 68-126, 138, 145, 147-213.)

Defendants' practices not only resulted in fraudulent claims being submitted to Medicare and Medicaid but also exposed cancer patients, whose immunity is already compromised, to contamination from the harvesting of the overfill. (*Id.* ¶¶ 2, 6, 10 171.) Defendants' practices violated the FDA's Current Good Manufacturing Practices ("CGMPs"), the United States Pharmacopeia ("USP") guidelines, and FDA labeling requirements. (*See, e.g.*, *id.* ¶¶ 74-75, 78, 84 96-100, 151.) The resulting syringes were not only adulterated but also misbranded. (*See, e.g.*, *id.* ¶¶ 192-213.) Moreover, Defendants' practice of offering the discounted overfill to providers resulted in an unlawful kickback to the providers for purchasing Defendants' syringes. (*Id.* ¶¶ 7, 24, 218-19, 233.)

ARGUMENT

I. OMNI'S ACTION IS NOT "RELATED" TO *UNDERWOOD* AND THUS IS NOT BARRED BY THE FIRST-TO-FILE RULE.

A. Defendants Incorrectly Construe the First-to-File Rule.

The "chief purpose" of the False Claims Act is "to provide for restitution to the government of money taken from it by fraud." *United States v. Bornstein*, 423 U.S. 303, 314 (1976) (quoting *United States ex rel. Marcus v. Hess*, 317 U.S. 537, 551-52 (1943)). The first-to-file rule achieves this goal in two ways: First, the rule encourages relators to commence their actions and present their knowledge of fraud to the government promptly by "protecting the first relator from either a race to judgment or dilution of any recovery his [or her] suit might produce." Brief for the United States as Amicus Curiae Supporting Respondent, *Kellogg Brown & Root Servs, Inc. v. United States ex rel. Carter*, 135 S.Ct. 1970 (2015) (No. 12-1497), 2014 WL 5395798, at *29; *United States ex rel. Wood v. Allergan, Inc*, 899 F.3d 163, 167 (2d Cir. 2018) ("The first-to-file bar ensures that only one relator shares in the Government's recovery and encourages potential relators to file their claims promptly."); *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Baxter Healthcare Corp.*, 772 F.3d 932, 937 (1st Cir. 2014) (quoting *United States ex rel. Wilson v. Bristol-Myers Squibb, Inc.*, 750 F.3d 111, 117 (1st Cir. 2014)) (rule "'provides incentives to relators to promptly alert the government' of any fraud.") If the two actions are not "related," "the two relators are not fighting over the same spoils" and the "first relator's recovery remains unaffected whether the second relator files or not." *In re Nat. Gas Royalties Qui Tam Litig.*, 566 F.3d 956, 963-64 (10th Cir. 2009).

Second, the rule—by prohibiting duplicative lawsuits—seeks to limit *qui tam* actions to only those that alert the government to new fraudulent claims for which the government can recover. *United States ex rel. Heath v. AT&T, Inc.*, 791 F.3d 112, 123 (D.C. Cir. 2015) (first-to-file rule seeks

"to prevent copycat litigation, which tells the government nothing it does not already know.").[2] A subsequent complaint is barred **only** if "the first-filed complaint ***ensures*** **that the Government 'would be equipped to investigate' the fraud alleged** in the later-filed complaint." *Wood*, 899 F.3d at 169 (quoting *Heath*, 791 F.3d at 121) (emphasis added); *United States ex rel. Capella v. United Techs. Corp.*, No. 3:94-CV-2063 (EBB), 1999 WL 464536, at *9 (D. Conn. June 3, 1999) (Court asks "whether the earlier and later actions possess the typical qualities of a parasitic relationship, such that the subsequent suit receives support or advantage without offering any useful or proper return").

When it is applied correctly, the first-to-file rule also protects defendants against duplicative lawsuits or exposure to double damages. *United States ex rel. Dorsey v. Dr. Warren E. Smith Cmty. Mental Health/Mental Retardation & Substance Abuse Ctrs.*, No. CIV.A 95-7446, 1997 WL 381761, at *3-4 (E.D. Pa. June 25, 1997) ("The purpose of the barriers articulated in sections 3730(b)(5) and 3730(e)(3) is to prevent double recovery by parasitic lawsuits."); Helmer 509 (consistent with "[t]he intended effect of Section 3730(b)(5)," the rule acts to "preclude a double recovery from defendants for the same conduct").

Critically, however, in the most recent U.S. Supreme Court case interpreting the provision, a ***unanimous*** U.S. Supreme Court directed courts ***not to construe the first-to-file rule in a way that immunizes defendants from liability*** or prevents the government from recovering for fraudulent claims. *Carter*, 135 S.Ct. at 1979. Although the Court was interpreting the word "pending" as opposed to "related" in the first-to-file rule, it emphasized the "strange" outcome that would result if the first-to-file rule were interpreted to immunize a guilty defendant from liability. Numerous courts and experts in the field concur that the first-to-file rule was never meant to immunize defendants from

[2] *See also Ven-A-Care*, 772 F.3d at 937 (duplicative lawsuits are precluded because they do nothing to satisfy the "purpose of the *qui tam* action under § 3730(b)," which is to provide the government with "genuinely valuable information" concerning fraud so it can recover funds to which the government is entitled); Boese § 4.03[C][2] ("The first-to-file bar was intended to prevent relators from litigating parasitic suits that provide no additional benefit to the public and would simply represent a drain on the government's recovery.").

wrongdoing or to eliminate any recovery by the government. *Heath*, 791 F.3d at 123 ("The point of the first-to-file bar is not to allow isolated misconduct to inoculate large companies against comprehensive fraud liability."); *United States v. Organon USA, Inc.*, No. H-08-3314, 2013 WL 12142351, at *31 (S.D. Tex. Feb. 1, 2013) ("The first-to-file bar was not intended to immunize defendants from liability from their own wrongdoing . . . ."); Helmer 507 ("The purpose of the 1986 Amendments to the FCA, including Section 3730(b)(5), was to reduce the obstacles to *qui tam* suits, not to institute them[.]").

Thus, construing the first-to-file rule in accordance with recent, unanimous U.S. Supreme Court guidance, the relevant canons of statutory interpretation, and its legislative intent, a second-filed action is "related" to a first-filed pending action **only if** it:

(1) incorporates "the same material elements of fraud" or the "same essential facts" as the earlier action, even if the allegations incorporate additional or somewhat different facts or information; and

(2) does not give rise to a separate and distinct recovery by the government.

Wood, 899 F.3d at 169 (2018) (quoting *Heath*, 791 F.3d at 121 and *Wilson,* 750 F.3d at 117); *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 232-34 (3d Cir. 1998) (second action "related" if it alleges all the essential facts of first, even if adds different or additional details, if it would not produce additional recovery or assistance for government); *United States ex rel. Batiste v. SLM Corp.*, 740 F. Supp. 2d 98, 102 (D.D.C. 2010) (quoting *United States ex rel. Ortega v. Columbia Healthcare, Inc.*, 240 F. Supp. 2d 8, 13 (D.D.C. 2003)) (action not "related" if it "gives rise to separate and distinct recovery by the government"; *Capella*, 1999 WL 464536, at *9 (same); *Erickson ex rel. United States v. Am. Inst. of Biological Scis.*, 716 F. Supp. 908, 918 (E.D. Va. 1989) (same); Boese § 4.03[C][2][a][ii] (discussing two-pronged analysis); Helmer 520 (same).

As set forth in detail below, Defendants urge this Court to dismiss Omni's action even though it alleges an entirely different fraudulent scheme, against a different group of defendants (and an

entirely different industry segment), and involving different drugs, and a different time period, and, even though the action, if successful, would result in the government's collection of hundreds of millions of dollars in fines and penalties with regard to entirely different false claims from those at issue in *Underwood* – a case that was voluntarily dismissed resulting in $0 recovered by the government.

B. Omni's Action Is Not Based On the Same Material Elements Of Fraud or the Same Material Facts Alleged in Underwood.[3]

McKesson makes essentially two arguments: First, it notes that there have been several overfill cases filed already, so it alleges this case is just a "copy cat" lawsuit. Second, it argues that the government was apprised of McKesson's fraud because the *Underwood* complaint names US Oncology among the 48 entities that had some involvement with overfill. Neither argument survives scrutiny.

1. Omni's Action Involves Almost Exclusively Different Defendants.

There is absolutely no authority, and McKesson cites none, that holds that a qui tam complaint alleging a particular fraudulent scheme bars all other cases in which *other* defendants commit an entirely independent fraud involving some of the same elements. *In re Nat. Gas Royalties Qui Tam Litig. (CO2 Appeals)*, 566 F.3d at 962 ("While we might consider a complaint that alleges an additional method of defrauding the government to state the same essential claim, we would not consider a complaint against an entirely different defendant to be stating the same claim.") "There is

[3] Defendants compare Plaintiff's Second Amended Complaint ("SAC") (filed 4/3/2018) to the *Underwood* complaint, but this Court's previous rulings indicate that any such comparison should be made between Plaintiff's original complaint (filed 3/12/2012) and the *Underwood* complaint. *See United States ex rel. Hanks v. Amgen, Inc.*, 2018 WL 4409832, at *19 (E.D.N.Y. Sept. 17, 2018) ("the determination of relatedness is made as of the time the later-filed action is brought"), citing *United States ex rel. Wood v. Allergan, Inc.*, 899 F.3d 163, 172 (2d Cir. 2018). Although the SAC adds additional distributors, the analysis remains the same.

a difference between a relator who simply tacks on an additional piece of evidence (a secret memo admitting to the fraudulent scheme, for instance) and a relator who alleges a scheme committed by a different party." *Id*. *United States ex rel. Pfeiffer v. Ela Medical, Inc*. 2010 WL 1380167, at *7 (D.Col. March 32, 2010) (in order for second action to be barred, claims "must be asserted against the same defendants").

The identity of the defendants is obviously critical to a first-to-file analysis. It is beyond cavil that "the identity of a defendant constitutes a material element of a fraud claim." *CO2 Appeals,* 566 F.3d at 962; *United States ex rel. Branch Consultants v. Allstate Ins. Co.,* 560 F.3d 371, 380 (5th Cir.2009) (holding that § 3730(b)(5) did not bar suit against unnamed, unrelated defendants); *see also United States ex rel. Trombetta v. EMSCO Billing Servs., Inc.*, Nos. 96 C 226, 99 C 151, 2002 WL 3453515, at *2 (N.D. Ill. Dec. 5, 2002). Indeed, many of the first-to-file cases Defendants rely on either did not name new defendants or, if they named new defendants, involved an earlier-filed action that had already discussed those defendants in some form.

Here, Omni is suing eight defendants, including McKesson Corporation and seven of its affiliates. The *Underwood* complaint named forty-nine defendants: thirteen "Defendant Manufacturers"; twenty-two "Defendant Repackagers"; and fourteen "Defendant Health Care Providers." When the *Underwood* action was filed, ***not one*** of the forty-nine defendants was even affiliated with McKesson. US Oncology, Inc.—the *only* defendant named in both complaints and sued by Omni for its role in a detailed fraudulent distributor scheme orchestrated by McKesson and its affiliates—***was not owned by McKesson*** at the time it was sued by *Underwood*, and was ***not even acquired by McKesson until December 30, 2010***, months after the *Underwood* action was brought.

2. Omni Alleges a Different Fraudulent Scheme Than Underwood, With Different Allegations of Wrongful Conduct In a Different Industry Segment.

While both *Underwood* and Omni discuss pharmaceutical products that contain overfill when

manufactured, the risks associated with subsequent adulteration and misbranding, and the resulting use of illegal kickbacks, the similarities end there. *Underwood* specifically alleged that *only* "[t]hree categories of Defendants [were] involved" in the fraudulent scheme that it outlined: Defendant Manufacturers, Defendant Repackagers, and Defendant Health Care Providers. (*Underwood* Compl. ¶ 6.) As to Defendant Manufacturers, *Underwood* stated that the named manufacturers, "[d]riven by competition and the desire to increase market share," intentionally put unnecessary excess biologic product exceeding the quantity noted on the container and/or in excess of the dose required for a patient ("overfill") into various containers so the manufacturers could use kickbacks to encourage health care providers to purchase the Defendant Manufacturers' products instead of other competitor manufacturers who made equivalent biologics. (*Underwood* Compl. ¶¶ 8, 10, 155.)[4] The repackagers were compounding pharmacies[5] that removed the overfill and repackaged it for providers who admitted the drug to patients.

Nowhere does *Underwood* allege that the manufacturer defendants were providing overfill for the purpose of selling it. Indeed, exactly the opposite: they were giving it away to the providers. Yet, that lies at the heart of Omni's claims; McKesson was harvesting overfill so that it could sell the overfill to providers at a discount, and the providers could, in turn, bill Medicare and Medicaid for that overfill. SAC, ¶ 223; Orig. Comp., ¶11. This distinction alone was sufficient for the court in *Saldivar v. Fresenius Medical Care Holdings, Inc*., 157 F. Supp. 3d 1311, 1326-27 (N.D. Ga. 2005) *reversed on other grounds* 841 F.3d 927 (11th Cir. 2006) to conclude that, where the first and second

[4] Underwood vilified the manufacturers' act of inserting and marketing overfill and used "the term 'overfill' to include both schemes, namely, exceeding the labeled quantity or the dose recommended for a patient." (Underwood Compl. ¶ 8; *see also id.* ¶ 150.)

[5] Compounding pharmacies are entities that are licensed by state law to mix and formulate FDA-approved drugs to accommodate for specific patients' needs. 21 U.S.C.A. § 353a (Compounding Pharmacies).

actions were against the *same defendant* and both actions charged defendant with harvesting overfill, the first action did not bar the second because the first one was "concerned with billing for overfill '*as though it came from new vials,*'" while the second action dealt with "billing for overfill *per se*." *Id*.

Further, with respect to all Defendants, including US Oncology, Omni alleges that Defendants themselves—at distribution facilities (that were not licensed compounding pharmacies), in non-aseptic conditions, with inappropriately trained and attired employees, and without proper compliance programs or oversight—actually compounded drugs, although not licensed to do so, by harvesting overfill, pooled the extracted drug product to create mislabeled pre-filled syringes (delivery containers that were not appropriately labeled, stored or shipped), and then distributed and billed providers for their adulterated and misbranded products, offering kickbacks to healthcare providers to buy in bulk from their Pre-Filled Syringe Program, and causing healthcare providers to submit false claims. It further alleges that McKesson hid this illegal harvesting from the FDA. (SAC ¶¶ 7, 10-13, 17, 21-26, 146, 220, 224, 231; *See also* Orig. Comp. ¶¶ 80, 105). *Underwood* did not address or focus on the environment of the repacking or the container of the repacked drugs.

3. Omni's Action Involves Additional Drugs Not At Issue In Underwood.

When a later-filed action alleges fraud pertaining to different or additional drugs beyond those alleged in a first-filed action, this fact is critical to the first-to-file analysis. *United States ex rel. Wood v. Allergan*, *Inc*., 246 F. Supp. 3d 772, 792 (S.D.N.Y. 2017), *rev'd and remanded on other grounds*, 899 F.3d 163 (2d Cir. 2018). "[T]he drug itself is an essential element of the fraudulent scheme alleged" against a defendant. *United States ex rel. Banigan v. Organon USA Inc*, 883 F. Supp. 2d 277, 291 (D. Mass. 2012) (a defendant's "prior involvement in a scheme involving specific pharmaceutical manufacturers and drugs does not mean that it necessarily engaged in such fraudulent conduct with other manufacturers or drugs."); *cf. In re Pharm. Indus. Average Wholesale Price Litig.*,

No. 01-CV-12257 (PBS), 2008 WL 2778808, at *3 (D. Mass. July 15, 2008) (finding that "the failure to specify the drug . . . in the earlier action constitutes a failure to state all the essential facts under the 'same material elements' standard"). As a result, even if the new drugs alleged were produced by the same manufacturer, the proposition may still "call for allowing an FCA suit against a pharmaceutical company to proceed notwithstanding an earlier-filed FCA suit against the same company, but involving a completely unrelated drug." *Wood*, 246 F.Supp. at 792. (further emphasizing that the "new" drugs in *Wood* were distributed through the same specific process by the same manufacturer as that alleged in the first-filed action).

Omni's action focuses on six specific pharmaceutical products used in Defendants' fraudulent Pre-Filled Syringe Program, three of which—Aloxi, Taxotere, and Kytril—are entirely new drugs that were not at issue in *Underwood* and which: (i) were not even manufactured by the named Defendant Manufacturers;[6] and (ii) are not biologics; they are classified as drugs which, in turn, are governed by different statutes, regulations and handling guidelines.[7] (*Cf. Underwood* Compl. ¶¶ 2, 148.) For this reason among the others alleged herein, the government could not have been put on notice of the fraud at issue, and the first-to-file rule does not apply with respect to the drugs newly alleged by Omni.

4. Omni's Claims Involve a Different Time Period Than Underwood.

Omni's complaint alleges a fraudulent Pre-Filled Syringe Program masterminded and perpetrated by the McKesson Defendants from 2001 to 2010, while *Underwood* focuses on a different scheme masterminded and perpetrated by biologics manufacturers between 1986 and 2005—the only

[6] Kytril is manufactured by an unnamed affiliate, however, of Roche.

[7] The distinction between drugs and biologics is critical here, particularly given that the FDA's approval process for biologics (a Biologics License Application under the Public Health Service Act) is different from its process for drugs (a New Drug Application under the federal Food, Drug, and Cosmetic Act), as is the way the FDA thereby defines the two categories of drug products.

period in which he purports to have knowledge.[8] Therefore, Omni seeks to recover on behalf of the governments for a different fraudulent scheme, perpetrated by different defendants with respect to some different drugs, in a different time period, than the scheme outlined in *Underwood*.[9]

5. The Fact that US Oncology is Named in Both Actions Does Not Bar Omni's Claims.

McKesson also makes the argument that the presence of US Oncology in both actions constitutes a bar to all the allegations in Omni's complaint. That argument lacks merit for two reasons: First, the allegations in this complaint against US Oncology are different and broader than those made in *Underwood*. Second, the allegations against US Oncology in *Underwood* could not have apprised the government of the acts of McKesson and its other subsidiaries, all of which took place before McKesson acquired US Oncology and are entirely separate from the acts alleged in *Underwood*.

(a) Omni's Claims Against US Oncology Are Different Than Underwood's.

Underwood generically alleges that (14) fourteen health care providers, with the assistance of the repackagers or through in-house pharmacies, administered the overfill to patients. *Underwood* Com. at ¶ 9. US Oncology is then listed as one of these providers which "purchases … and/or manipulates and repackages" biologic drugs in violation of law. *Id*. at ¶ 76.

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[8] *Underwood* was based upon the Relator's time at Genentech from 1986 through February 2005. (Underwood Compl. ¶¶ 23, 147-48.) Indeed, the Relator specifically claimed that his experience prior to his departure from Genentech in February 2005 "conferred upon him direct knowledge of the illegal practices alleged in this Complaint" as he "met with health care providers who purchased and administered biologic drugs and [] regularly interacted with marketing representatives and executives from manufacturers." (*Id.* ¶ 148.) As Omni's claims are based on Omni's personal experience with the McKesson Defendants, the Omni action could not have been a parasitic or copycat litigation.

[9] Here again, McKesson's reliance on cases holding that subsequent actions involving different time periods are still "related" under the first-to-file rule, is misplaced. Unlike Omni and as detailed below, those cases involved first-filed complaints against or referring to the same defendant, and/or involve allegations of the same fraudulent conduct and/or with respect to the same drugs, such that the first-filed complaint put the government on notice of the defendant's conduct.

Omni's allegations are materially different in kind. Omni specifically alleges that US Oncology physicians themselves, not an in-house pharmacy, harvested overfill from vials for treatment of patients. SEC ¶ 146. Further, it also specifically alleges that US Oncology profited from distributing syringes created from overfill to other providers. *Id*. None of those allegations appear in the *Underwood* complaint and, therefore, cannot be barred by the *Underwood* allegations.[10]

Moreover, to the extent there is overlap in the allegations that US Oncology submitted false claims, such claims could only potentially overlap with respect to the three biologics named in common, and only during 2001-2005. But it is nevertheless impossible that US Oncology's submission of false claims for those three adulterated and misbranded biologics between 2001 and 2005 were caused by the same defendants. For any particular false claim, US Oncology as a healthcare provider would only have purchased those biologics from either the other McKesson defendants, or one of the *Underwood* Defendants, or some other source. No purchase resulting in a false claim would have been sourced by both McKesson and the *Underwood* defendants. Thus, there is no duplication in claims made in the two complaints.

(b) Even If, Arguendo, Omni's Claims Against US Oncology Were the Same, Any Dismissal Would Not Extend to the Other McKesson Defendants.

Even if Omni's claims against US Oncology were the same as *Underwood's* (and they are not), any overlap cannot possibly bar the claims against McKesson, OTN and other subsidiaries that

[10] To the extent that Underwood's vague allegations against US Oncology could provide "sufficient notice for the government to initiate an investigation," *United States ex rel. Kelschenbach v. M&T Bank Corp*., No. 13-CV-280S, 2017 WL 1046335, at *3 (W.D.N.Y. Mar. 20, 2017) (internal quotations omitted), Omni's complaint includes allegations that alert the government to additional ways in which US Oncology engaged in fraud, *cf. United States ex rel. Duxbury v. Ortho Biotech Prods., L.P*., 579 F.3d 13, 32-34 (1st Cir. 2009) (later-filed action not barred by first-to-file rule, where, although earlier-filed action already alleged that same defendant engaged in off-label promotion scheme for same drug, later-filed action also alleged additional ways in which defendant engaged in off-label promotion for that drug).

were actively involved in the harvesting of overfill, none of which is alleged in the *Underwood* complaint.

McKesson appears to be arguing that Underwood's vague reference to US Oncology's "affiliates" *ex post facto* implicates McKesson and all the subsidiaries. But, at the time the *Underwood* complaint was filed on May 28, 2010, US Oncology had no relationship with McKesson. McKesson did not acquire US Oncology until December, 2010 (SAC ¶ 44) so no allegation in *Underwood* would have apprised the government that an entity that acquired US Oncology, after *Underwood* was filed, was also involved in an entirely separate scheme. By acquiring US Oncology in 2010, McKesson succeeded to US Oncology's liability, but that acquisition did not put the government on notice of McKesson's *own* illegal acts before that acquisition.

McKesson does not cite, and Omni has not been able to locate, precedent to dismiss an action against a parent corporation and its affiliates when: (i) the parent was never named, described in or relevant to the first-filed action; (ii) the parent did not even acquire the subsidiary named in the first-filed action until after the complaint was filed; and (iii) the first complaint made no allegations of industry-wide wrongdoing that would have caused the government to investigate the subsequently acquiring parent company and its affiliates, even if the alleged fraudulent schemes were the same—much less a case where the fraudulent schemes and wrongdoing in the two complaints are (as here) different.

The primary cases relied upon by McKesson, *United States ex rel. Hampton v. Columbia/HCA Healthcare Corp*., 318 F.3d 214 (D.C. Surr. 2003); *Grynberg v. Koch Gateway Pipeline Co*., 390 F.3d 1276, 1280, n.4 (10th Cir. 2004) are clearly distinguishable. In *Hampton*, the court held that the first complaint clearly alleged a "corporate-wide" fraud in which the parent perpetrated the fraud through a number of subsidiaries. Thus the government was clearly placed on notice from the original complaint. Similarly, in *Grynberg*, where both complaints alleged the exact same corporate-wide

conspiracy, the court held in a footnote that adding an additional subsidiary is not enough to avoid the first-to-file rule. *See Branch Consultants*, 560 F.3d at 379 (explaining the rationale of *Hampton* and *Grynberg*). The fact that US Oncology was alleged to be billing for products containing overfill or provided by manufacturers would not have placed the government on notice that McKesson, in an entirely separate scheme, was harvesting overfill and selling it to providers.[11] *Heath*, 791 F.3d at 121-22 (first-filed action which alleged that a Wisconsin subsidiary of AT&T was defrauding the government through improper charges was not sufficient to put the government on notice of a broader, nationwide scheme to defraud the government, as alleged in the second action).

Indeed, if Defendants' argument were correct, corporations (from the smallest to the largest conglomerates responsible for billions of dollars of false claims) could immunize themselves from FCA liability by intentionally acquiring companies already accused of, investigated, or sued for engaging in misconduct.

C. Omni's Action Gives Rise To A Separate and Distinct Recovery By the Government and Would Not Lead to a Double Recovery.

Although it is a purely hypothetical exercise (because *Underwood* was voluntarily dismissed a few months after it was unsealed and thus led to the government recovering nothing in connection

[11] The other cases on which McKesson relies are wholly inapposite. *See, e.g.*, *United States v. Medco Health Sols., Inc.*, No. 11-684-RGA, 2017 WL 63006, at *11 (D. Del. Jan. 5, 2017) (unnamed defendant was "expressly identified" in earlier-filed action as one of two participants in alleged conspiracy and mentioned in that complaint "no fewer than fifty times"); *United States ex rel. Szymoniak v. ACE Sec. Corp.*, No. 0:13-cv-00464-JFA, 2014 WL 1910876, at *5 (D.S.C. May 12, 2014) ("[M]any corporate defendants in [later-filed case] were represented already in [earlier-filed] case"—including the same five major banks—and earlier-filed case included "allegations of industry-wide fraud"); *U.S. ex rel. Powell v. American InterContintenal University, Inc.,* No. 08-cv-2277, 2012 WL 2885356, at *6 n.5, *9 (N.D. Ga. July 12, 2012) (relator conceded that *only* difference between complaints was that later-filed complaint named wholly-owned subsidiary as additional defendant); *U.S. ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d at 123-24 (D. Ma. Feb. 25, 2011) (though in the context of public disclosure bar, first-filed complaint involved company that was a subsidiary of the parent company, later named, at the time the first-filed complaint was filed, and also named the drug produced by the parent company).

with the fraud alleged therein), it is clear that even if *Underwood* had been pursued, Omni's action would (and will) lead to a separate and distinct recovery by the government and that Defendants have no exposure to double damages. The false claims that Defendants submitted and caused to be submitted, and that are the basis for Omni's action seeking damages and penalties against them, are different than those for which the government could have feasibly recovered in *Underwood* for at least three independent reasons.

First, Underwood names different defendants and is based on those defendants' overfill placement and harvesting for which the *Underwood*-named providers sought reimbursement. This action necessarily involves different false claims, *i.e.*, for syringes *created by McKesson* and sold to providers who made entirely different requests for reimbursement.

Second, as explained in great detail *supra* at I(B)(3), many of the actual false claims submitted were for drugs that were entirely different from the biologics at issue in *Underwood*, such that the government could not have feasibly recovered any damages or penalties for false claims submitted in connection with those drugs during the 2001-2010 time period alleged by Omni.

Third, *Underwood* appears to seek damages for false claims submitted between 1986 and 2005, thus there is no possible overlap in claims even with respect to the three jointly named biologics for the period of 2005 to 2010.

Thus, the only even remotely possible overlap *between* the false claims challenged here and *Underwood* would be claims submitted for the three biologics—Aranesp, Neupogen, and Procrit—in pre-filled syringes, between 2001-2005 by US Oncology, Inc. But even those claims were unlikely to overlap because the source of the overfill, and therefore the false claims submitted to Medicare and Medicaid, are different: One group would be for overfill manufactured by the *Underwood* defendants and the other harvested by the McKesson defendants. Therefore, the instant action is not related to *Underwood* because the Omni action gives rise to a separate and distinct recovery by the government.

II. THE SECOND AMENDED COMPLAINT SATISFIES RULE 9(B).

Claims brought under the False Claims Act are subject to the requirements of Rule 9(b). *United States v. N. Adult Daily Health Care Ctr.,* 205 F. Supp. 3d 276, 285 (E.D.N.Y. 2016). But "[t]he pleading standard under Rule 9(b) may be relaxed where '(1) the facts are peculiarly within the possession and control of the defendant or (2) where the belief is based on factual information that makes the inference of culpability plausible." *N. Adult*, 205 F. Supp. 3d at 289 (quoting *Arista Records, LLC v. Doe*, 604 F.3d 110, 120 (2d Cir. 2010)). "It is not the purpose of Rule 9(b), as applied to FCA *qui tam* actions, to render the FCA toothless as to particularly clever fraudulent schemes." *United States ex rel. Chorches as Tr. for the Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 86 (2d Cir. 2017). While Rule 9(b) "demands specificity . . . it does not elevate the standard of certainty that a pleading must attain beyond the ordinary level of plausibility." *Id.* at 88. And, "if a relator alleges facts supporting a strong inference that the defendant violated the FCA but there is a dispute regarding whether Rule 9(b) has been entirely satisfied, the proper resolution may be a targeted discovery process rather than outright dismissal." *United States v. Visiting Nurse Serv. of N.Y.* 14-CV-5739 (AJN), 2017 WL 5515860, at *14 (S.D.N.Y. Sept. 26, 2017).

A. Omni Adequately Alleges False Claims By Other Healthcare Providers.

McKesson argues (at 13-17), that the Court should dismiss all claims concerning the submission of false claims by anyone other than Omni for an alleged failure to satisfy Rule 9(b) requirements, including identifying who submitted such claims, when, and what they *said*, and that such information is not peculiarly within McKesson's knowledge. McKesson is wrong.

"A complaint can satisfy Rule 9(b)'s particularity requirement by making plausible allegations creating a strong inference that specific false claims were submitted to the government and that the information that would permit further identification of those claims is peculiarly within the opposing party's knowledge." *Chorches*, 865 F.3d at 86; *United States ex rel. Gelman v. Donovan*, No. 12 CV

5142 (RJD), 2017 WL 4280543, at *6 (E.D.N.Y. Sept. 25, 2017) (same). When the fraudulent scheme is extensive and occurs over a long period time, plaintiffs can satisfy 9(b) by: "(1) providing sufficient identifying information about all the false claims, or (2) providing example false claims." *Visiting Nurse*, 2017 WL 5515860, at *14 (quoting *United States ex rel. Kester v. Novartis Pharm. Corp.*, 23 F. Supp. 3d 242, 258 (S.D.N.Y. 2014) (same)); *N. Adult*, 205 F. Supp. 3d at 289 ("relator need allege only 'representative samples' of fraudulent conduct to satisfy Rule 9(b)").[12]

Here, the SAC: (i) gives extensive details about the exact *McKesson* Defendants and their role in the illegal Pre-Filled Syringe Program, (ii) identifies the exact six drugs, (iii) discusses Defendants' marketing of that program to Omni and other oncology practices, (iv) attaches Defendants' order form distributed to health care providers for use in the program, (v) attaches specific examples of fraudulent claims actually submitted, and (vi) alleges that similar conduct by McKesson's competitor led to guilty pleas with fines and penalties (all tied to false claims submitted) of $1 billion. (*See generally* SAC.) The SAC is thus sufficient under well-established law which simply requires the complaint to "provide a factual basis to support the plaintiff's assertion that claims were actually submitted" to the government, but does not require proof of every iteration of a defendant's false claims that may have been submitted to the government. *United States ex rel. Kester v. Novartis Pharm. Corp.*, No. 11-cv-8196, 2015 WL 109934, at *24 (S.D.N.Y. Jan. 6, 2015).[13]

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[12] *See also United States ex rel. Matheny v. Medco Health Sols., Inc.*, 671 F.3d 1217, 1226-27 (11th Cir. 2012) ("inclusion of some records for some of the accounts is sufficient."); *United States ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1358-59 (11th Cir. 2006) (while dates, amounts, and account numbers can provide particularity, Rule 9(b) mandates only that "some of the information for at least some of the claims" be included); *United States ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C.*, 318 F. Supp. 3d 680, 702 (S.D.N.Y. 2018) (submitting examples of "small fraction" of loan documents sufficient); *United States v. Wells Fargo Bank, N.A.*, 972 F. Supp. 2d 593, 616-17 (S.D.N.Y. 2013) (ten sample insurance claims sufficient).

[13] To the extent that the Court requires additional claims to be pled, Relator has engaged in informal collection of data from State Attorney General Offices, and can amend the SAC with additional representative claims.

Moreover, like in *Chorches*, "the information that would permit further identification of those claims"—namely, the customer lists of providers to whom Defendants sold pre-filled syringes—is "peculiarly within the opposing party's knowledge." *Chorches*, 865 F.3d at 82, 86.

B. Omni Pleads Individualized Misconduct.

Defendants assert that Omni failed to distinguish between the various defendants and failed to plead improper conduct by individual defendants other than U.S. Oncology and OTN. (Defs.' Mem. 17-18.). This is not correct.

Rule 9(b) requires "[n]o more" than "that the Complaint gives each defendant notice of precisely what he is charged with," *Goldman v. Belden*, 754 F.2d 1059, 1070 (2d Cir. 1985), which can be accomplished by alleging "the 'who,' 'what,' 'where,' 'when,' and 'how' requirements for pleading fraud," even if the complaint "groups defendants together 'into one wrongdoing monolith.'" *United States ex rel. Taylor v. Gabelli*, 345 F. Supp. 2d 313, 339-40 (S.D.N.Y. 2004). Rule 9(b) is also satisfied where, as Omni does here, the plaintiff alleges that the particular defendant "knew of, or participated in, the fraud." *See Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993).[14]

Nevertheless, Rule 9(b)'s particularity requirement is relaxed where, ***as here***, "a case involves complex or extensive fraudulent schemes," *Gabelli*, 345 F. Supp. 2d at 326, "the fraudulent conduct is alleged to have taken place over a number of years," *id.*, information concerning the alleged fraud may be exclusively within the defendants' possession, *ASTI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493

[14] McKesson's reliance (at 17) on unpublished *United States ex rel. Oughatiyan v. IPC The Hospitalist Co., Inc.*, No. 09 C 5418, 2015 WL 718345, at *6-7 (N.D. Ill. Feb. 17, 2015) is misplaced. Unlike Omni, plaintiffs in that case only alleged that the parent company, not the subsidiaries, submitted false claims and "did not explain what role IPC's subsidiaries and affiliates played in the alleged fraud." Omni outlines in detail the role played by each defendant as well as the parent company's intentional expansion internally and by acquisition of the illegal program, and its assumption of relevant liabilities. (*See, e.g.*, SAC ¶¶ 11-12, 19, 26, 38-49.)

F.3d 87, 101-02 (2d Cir. 2007), or the defendant defrauded a third party, *United States v. Rivieccio*, 661 F. Supp. 281, 290 (E.D.N.Y. 1987).[15] Even if fraud is not separately alleged with particularity against each defendant, "[d]ismissal on the ground that facts within [the defendants'] knowledge have not yet been proven in the pleading stage [is] particularly inappropriate." *DGM Invs., Inc. v. N.Y. Futures Exch., Inc.*, 265 F. Supp. 2d 254, 264 (S.D.N.Y. 2003).

Even if this relaxed standard were not applied, Omni alleges fraud with sufficient particularity to satisfy the ordinary Rule 9(b) standard because it pleads the "who", "what" "where" "when", and "how" of Defendants' fraud (SAC ¶¶ 6, 19, 137, 144-45, 165, 173, 182, 217-18.) Moreover, the SAC makes clear distinctions among, and particularized allegations against, the various defendants with respect to their role and level of participation in the fraud, and details a specific visit to OTN facilities on August 28, 2007, during which Omni's principal witnessed the alleged fraud. Accordingly, the Court should deny McKesson's motion to dismiss Omni's claims against all defendants other than OTN and U.S. Oncology under Rule 9(b).[16]

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[15] "Because a qui tam suit asserts that a third-party has been defrauded, it is likely that the relators have limited knowledge of the specifics of the alleged fraud. Therefore, when facts are mostly within the perpetrator's knowledge, Rule 9(b) is relaxed. . . . Otherwise, Rule 9(b) would frustrate the purpose of the FCA and inhibit the ability of the United States to uncover fraud through relators acting on its behalf." *United States ex rel. Stewart v. The Louisiana Clinic*, No. CIV.A. 99-1767, 2002 WL 257690, at *2 (E.D. La. Feb. 22, 2002).

[16] Defendants include a single sentence stating that Omni's state FCA claims fail under Rule 9(b) for the same reasons as Omni's federal FCA claims. (*See* Defs.' Mem. 23.) However, Defendants cannot simply transfer their arguments, particularly given that at least two state statutes do not require the pleading of false claims. *See* Ga. Code Ann. § 23-3-123(c) ("[T]he qui tam plaintiff shall not be required to identify specific false claims that result from an alleged course of misconduct or any specific records or statements used if the facts alleged the complaint, if ultimately proven true, would provide a reasonable indication that one or more violations . . . are likely to have occurred and if the allegations in the pleading provide adequate notice of the specific nature of the alleged misconduct . . ."); N.Y. State Fin. Law § 192(1-a) (same). In any event, Defendants' argument fail for the reasons stated above.

III. OMNI'S CLAIMS SATISFY RULE 12(b)(6).

A. Omni States a Valid FCA Claim For McKesson's Overfill Fraud.

McKesson's first argument is simply a rehash of its Rule 9(b) argument, that Omni has supposedly failed to allege that anyone "actually submitted a claim for overfill." This argument fails for the reasons outlined in Section II above.

B. Omni States a Valid FCA Claim For McKesson's Manipulation of the ASP.

Omni has detailed the ways in which McKesson manipulated the ASP to inflate claims, (SAC ¶¶ 117-38; 217-32), but McKesson asserts (at 19), without a single citation, that unless Omni can prove what the actual ASP was "or should have been" absent manipulation, Omni's claim must be dismissed as "speculative" and "hypothetical." McKesson misapprehends the Rule 12(b)(6) standard. "The pleading of specific facts is not required; rather a complaint need only give the defendant 'fair notice of what the . . . claim is and the grounds upon which it rests.'" *Williams v. Bank of N.Y. Mellon*, No. 13-CV-6814 SJF GRB, 2015 WL 430290, at *3 (E.D.N.Y. Feb. 2, 2015). Plaintiff need not present proof or "show" that its claims are accurate. *United States ex rel. Rowe v. SI-BONE, Inc.*, No. 2:14-cv-179, 2016 WL 9344090, at *6 (D. Vt. Dec. 2, 2016).

Omni satisfies the pleading standard alleging that McKesson manipulated the ASP by excluding from its calculation McKesson's sales of the pre-filled syringes containing overfill. By excluding these sales, McKesson necessarily, as a result of the formulas, increased the ASP, thereby inflating the amounts it charged for the relevant products. (SAC ¶¶ 217-229) McKesson thus caused false claims to be made when providers sought reimbursement at artificially inflated ASPs. The fact that Omni has not, at the pleading stage, provided a precise calculation of what the ASP would have been but for McKesson's manipulation does not render Omni's allegations implausible; indeed, the information necessary for such a calculation – such as the amount of overfill McKesson harvested – is solely in McKesson's possession, and the sophistication necessary to transform such information into

a damages estimate is possessed by experts.

C. The Remainder of Defendants' Arguments About Omni's FCA Claims Do Not Meet the 12(b)(6) Standard for Dismissal.

Defendants' remaining arguments are equally unfounded. First, Defendants' claims that he SAC lacks "allegations about an actual false record or statement" under Section 3729(a)(2). But the SAC specifically alleges that Defendants caused providers to submit false claims for reimbursement for drugs that the manufacturer did not charge for. *See* SAC ¶ 11, 12, 22, 28, 214, 215.

Second, contrary to Defendants' assertion, this case does involve an obligation to the government: under federal law, a person who knowingly receives an overpayment from Medicare or Medicaid must return the surplus within sixty days. *See* 42 U.S.C. § 1320a-7k. As Omni alleges, US Oncology knowingly received overpayments from those government programs but failed to repay the surplus, and Defendants – acting as distributors – caused providers to receive overpayments from government programs and that providers knew that they were receiving those overpayments. (*See* SAC ¶¶ 214, 230, 237-38, 243-44.) These allegations are sufficient to state a claim under 31 U.S.C. § 3729(a)(7). "A claim under § 3729(a)(7) requires proof: (1) that the defendant made, used, or caused to be used a record or statement to conceal, avoid, or decrease an obligation to the United States; (2) that the statement or record was false; (3) that the defendant knew that the statement or record was false; and (4) that the United States suffered damages as a result." *United States v. Raymond & Whitcomb Co.*, 53 F. Supp. 2d 436, 444-45 (S.D.N.Y. 1999). An obligation to pay the government exists when a provider knowingly retains an overpayment from Medicare/Medicaid. *Kane ex rel. United States v. Healthfirst, Inc.*, 120 F. Supp. 3d 370, 383–96 (S.D.N.Y. 2015). Accordingly, Omni's allegations that Defendants knowingly caused providers to file false claims, providers knowingly retained the resulting overpayments, and Defendants failed to notify the government (thereby concealing providers' obligation), are both sufficient to state a claim under

§ 3729(a)(7).[17]

Third, Omni has alleged facts sufficient to state a conspiracy claim under 31 U.S.C. § 3729(a)(3). Omni has specifically pled that McKesson acquired OTN and US Oncology for the singular purpose of forming an entire business division devoted to these unlawful practices, among numerous other allegations demonstrating that Defendants were in agreement among themselves to continue manufacturing pre-filled syringes, including coordinated industry-wide pushes for the use of pre-filled syringes and discounts to healthcare providers for using those pre-filled syringes. (*See, e.g.*, SAC ¶¶ 26, 246-48.) Omni has also alleged myriad acts taken in support of that conspiracy. (*See, e.g.*, *id.* ¶¶ 137-39.) At this stage of the litigation, Omni's allegations suffice to state a conspiracy claim. *See Grubea*, 318 F. Supp. 3d at 705 ("To state a conspiracy claim, Relator must allege that '(1) the defendant conspired with one or more persons to get a false or fraudulent claim allowed or paid by the United States and (2) one or more conspirators performed any act to effect the object of the conspiracy.'" (citation omitted)).[18]

IV. OMNI'S CLAIMS ARE NOT TIME-BARRED.

All of Omni's claims are timely. Defendants' assertion that amended FCA pleadings cannot relate back to the original complaint because it was filed under seal is false, and the *Hayes* case cited by Defendants actually stands for the opposite proposition, as does the weight of authority in the

[17] Defendants also argue that Omni's § 3729(a)(7) Count should be dismissed as duplicative of the § 3729(a)(1) or (a)(2) counts. But Omni's § 3729(a)(7) allegations differ from those supporting its § 3729(a)(1) and (a)(2) claims because the former include allegations that (1) US Oncology knowingly retained overpayments, (2) other providers knowingly retained overpayments, and (3) Defendants failed to notify or reimburse the government. *Compare United States v. Mount Sinai Hosp.*, 256 F. Supp. 3d 443, 457 (S.D.N.Y. 2017) (dismissing § 3729(a)(7) claim on summary judgment, after denying motion to dismiss the claim, where plaintiff "rel[ied] on the same acts to substantiate the allegations" under § 3729(a)(1) and (a)(7)). It is also premature to determine whether the claims are duplicative with regard to the parent's conduct as opposed to its subsidiaries.'

[18] Omni can, and should be permitted to, cure any perceived defects via amendment.

Second Circuit, *i.e*. that amended pleadings filed by a relator in a sealed *qui tam* case *do* relate back to the original complaint. *Hayes v. Dep't of Educ. of City of New York*, 20 F. Supp. 3d 438, 444 (S.D.N.Y. 2014); *U.S. ex rel. Grupp v. DHL Exp. (USA), Inc*., 47 F. Supp. 3d 171, 179 (W.D.N.Y. 2014), *aff'd sub nom. U.S. ex rel. Grupp v. DHL Worldwide Exp., Inc*., 604 F. App'x 40 (2d Cir. 2015).[19]

The *Hayes* court also held that the "original sealed complaint tolled the applicable statute of limitations" where the amended claims arose out of the same conduct outlined in the original complaint. *Hayes*, 20 F. Supp. 3d at 444. Here, the claims added in the SAC relate back to the First Amended Complaint because they arose out of the same conduct and simply "'amplify the facts alleged in the [Original] pleading or set forth those facts with greater specificity' and thus arise out of the same conduct or occurrence as the claim originally pleaded." *Maccharulo v. Gould*, 643 F. Supp. 2d 587, 594 (S.D.N.Y. 2009) (quoting *In re Chaus Sec. Litig*., 801 F. Supp. 1257, 1264 (S.D.N.Y. 1992)).

The Second Circuit has also recognized that "the institution of an action against one party will constitute imputed notice to a party subsequently named by an amendment of the pleading when the parties are closely related in their business activities or linked in their corporate structure." *In re Allbrand Appliance & Television Co., Inc*., 875 F.2d 1021, 1025 (2d Cir. 1989); *also Sounds Express Int'l Ltd. v. American Themes and Tapes, Inc*., 101 F.R.D. 694, 697 (S.D.N.Y.1984) (entities have a close identity of interests). Omni's claims against the newly-added defendants relate back to the First Amended Complaint because they are either linked as wholly owned subsidiaries of the original

[19] *United States v. The Baylor Univ. Med. Ctr*., 469 F.3d 263, 268 (2d Cir. 2006) (superseded by statute) on which Defendants rely is inapposite. It analyzes Rule 15(c) in the context of a government's complaint in intervention, not whether a relator's complaint tolls the statute of limitations. This important distinction has been made repeatedly by courts in this Circuit *Hayes*, 20 F. Supp. 3d at 444, and *Grupp,* 47 F. Supp. 3d at 179.

McKesson Defendants or have a close identity of interests as successors-in-interest to, or the corrected legal names for, the original McKesson Defendants.

CONCLUSION

For the foregoing reasons, Omni respectfully requests that the Court deny Defendants' motion to dismiss.

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Respectfully submitted,

BOIES SCHILLER FLEXNER LLP

By: _____
George F. Carpinello
Teresa A. Monroe
30 South Pearl Street
Albany, New York 12207
Phone: (518) 434-0600
Fax: (518) 434-0665

Courtney Rockett
Lisa Sokolowski
333 Main Street
Armonk, New York 10504
Phone: (914) 749-8200
Fax: (914) 749-8300

Counsel for Relator Omni Healthcare, Inc.